

SEX DIFFERENCES IN BALANCE MEASURES AND CHRONIC LOW  
BACK PAIN IN OLDER ADULTS

by

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## Abstract

# SEX DIFFERENCES IN BALANCE MEASURES AND CHRONIC LOW BACK PAIN IN OLDER ADULTS

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The older adult population is growing at a rapid pace, with the US Census Bureau estimating older adults to comprise of 20% of the overall population by 2020.

Now, more than ever, we must parse out differences within this group to target their specific needs, particularly those concerning potential injury and pain. Older adults face unique challenges surrounding their ability to manage pain conditions, such as increased fall risk, increased medication use, decreased physical ability, and multimorbidities. As such, uncovering the most effective and cost-effective strategies for mobility and maintenance are of vital importance. Previous research indicates there are sex differences in such pain measures, which could provide valuable insight into pain management modalities and rehabilitation measures following injury or illness. The relationships of sex differences in balance measures, such as equilibrium, strategy, and overall balance, are not fully

understood, particularly in older adult populations. Relationships between balance and pain, specifically chronic low back pain (CLBP), are also poorly understood. The current study examined older adults ( $N = 144$ ) with and without chronic low back pain by means of the NeuroCom Balance Master, Senior Fit Test, PROMIS-29 Assessment. Each measure contributed unique biopsychosocial information such as facets of balance, aspects of pain, depression scores, sex, and physical ability. The current study aimed to: examine the relationship of sex and balance; examine the relationship of sex and pain; assess sex and balance as predictors of CLBP; and to look for moderating relationships of sex, balance, and pain. Results indicated there were not sex differences in pain aspects; there were significant effects of sex on balance measures; and the interaction between sex and balance significantly predicted CLBP likelihood.

*Keywords:* chronic low back pain, pain, balance, sex differences, older adults, biopsychosocial

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## Chapter 1

### Introduction

Older adults face numerous challenges with mobility and pain management. Whether due to natural aging processes or injury, there is a great need to identify, develop, and customize effective pain prevention and management strategies targeted to this age group. While such strategies are relevant to all ages, the unique circumstances surrounding older populations often require room for greater levels of customization and flexibility, particularly in physical domains such as strength and balance. Balance can be a highly influential factor in pain patients, where deficits can result in avoidance behaviors, falls, distress, and deconditioning which can exacerbate pain, trapping a patient in a vicious cycle (Boyd & Stevens, 2009; Bevers, Watts, Kishino & Gatchel, 2016; Maxwell, et. al., 2008; Hulla, Gatchel & Liegey-Dougall, 2017). Pain is prevalent and often undertreated among older adults, also contributing to increased fall risk, avoidance behaviors, and deconditioning (Maxwell, et. al., 2008; Naugle, 2016; Bevers, Brecht, Jones & Gatchel, 2018). Additionally, sex differences have been observed in how pain is experienced, described, and tolerated (Keogh & Eccleston, 2006; Fillingim, et. al., 2009; Lamb, et. al, 2000; Leveille, Ling & Hochberg, 2001; Leveille, Bean, Bandeen-Roche, Jones, Hochberg & Guralnik, 2002; Darnall & Sazie, 2012; Racine, Tousignant-Laflamme, Kloda, Dion, Dupuis & Choiniere, 2012; Bartley & Fillingim, 2013;

Morgan, Parker, Alvarez-Jimenez & Jorm, 2013; Stubbs, Binnekade, Eggermont, Sepehry, Patchay & Schofield, 2014; Hulla, Moomey, Garner, Ray & Gatchel, 2016; Lee, Biggan & Ray, 2016). It is important to examine the relationships between back pain, balance, and sex in older adults to distinguish responsible mechanisms and develop customizable prevention and pain management strategies. The following sections will discuss the concerns surrounding these measures specifically for older adults.

### *1.1 Balance Measures in Older Adults*

Balance measures are an important concern for older adults. Poor balance can lead to significant disability and injury, particularly in older populations, via falls, fractures, avoidance behaviors, anxiety, and decreased mobility (Deshpande, Metter, Lauretani, Bandinelli, Guralnik & Ferrucci, 2008; Kempen, Van Haastregt, McKee, Delbare & Zijlstra, 2009; Greenberg, 2012; Takeshima, Islam, Rogers, Koizumi, Tomiyama, Narita & Rogers, 2013; Hughes, Kneebone, Jones & Brady, 2015; Vermeulen, Neyens, Spreeuwenberg, van Rossum, Boessen, Sipers & de Witte, 2015; Hulla, Gatchel & Liegey-Dougall, 2017). One in three older adults falls annually, with 20-30% of those experiencing resultant disability (Freeman, et. al., 2002; Bishop, Patterson, Romero & Light, 2010; Donath, Van Dieen & Faude, 2016; Hulla, Gatchel & Liegey-Dougall, 2017). Falls are a leading cause of injury, disability, and premature death, particularly in older adults, and we know that age-related declines like muscle weakness and

deterioration, visual problems, and balance deficits all contribute to fall risk (Freeman, et. al., 2002; Delbaere, Crombez, Vanderstareten, Willems & Cambier, 2004; Moore & Ellis, 2008; Daniel, 2012; Hull, Kneebone & Farquharson, 2012; Hulla, Gatchel & Liegey-Dougall, 2017). Older adults are at increased risk of falls and fall-related injuries, leading to negative impacts on patient health, both physical and psychosocial (Chang, Morton, Rubenstein, Mojica, Maglione, Suttorp, Roth & Shekelle, 2004; Close, 2005; Gallagher, Rapuri & Smith, 2007; Duckham, et al. 2013). Fear-of-falling can lead to avoidance behaviors regarding exercise and social interactions, decreasing mobility, strength, and perceived social support, all of which are detrimental to overall quality-of-life (Stevens, Corso, Finkelstein & Miller, 2006; Berry & Miller, 2008; Davis, Robertson, Ashe, Liu-Ambrose, Khan & Marra, 2010; Duckham, et al., 2013; Burns, Stevens & Lee, 2016).

However, the relationships concerning balance measures are not fully understood. Balance problems may be hard to detect during routine physical examinations, and should be routinely tested in older adults or those at risk for fall injury (Greenberg, 2012). With increasing access to testing equipment, practitioners can abandon risky tests, such as standing on one leg or modified sobriety tests (Chaudhry, Bukiet, Ji & Findley, 2011). Fortunately, we have access to safe-testing mechanisms that can produce a range of data, including strategy preference, center of gravity, and overall postural control using the *NeuroCom*

*Balance Master* (NeuroCom) system (see Figure 1-1). The NeuroCom uses a force plate and three-sided surround to record balance during a series of timed trials. The conditions differed by having a stable or released force plate and surround, in addition to normal or absent vision (called the sensory organization test [SOT]). Outcome measures include strategy (hip-based and ankle-based); equilibrium (amount of sway or postural stability); sensory ratios for vestibular, visual, and somatosensory used to maintain balance; center of gravity alignment; and an overall composite score for balance.

Using the data from NeuroCom balance tests, the current study aims to distinguish how these factors differ by sex, further exploring the complicated relationship among sex, balance, and the pain experience. Sex differences in balance measures have produced some mixed results, particularly when observed in younger populations, such as a study done by Olchowik and colleagues (2015), which found no overall difference in balance composite scores between healthy 20-26 year old male and female participants using the NeuroCom. The study did find significant sex differences in equilibrium, measured by forward-backward sway representing center-of-gravity, such that men displayed significantly higher scores, representing a more unstable center of gravity and increased forward-backward sway (Olchowik, et. al., 2015). Furthermore, females in this study were more ankle-dominant in strategy compared to males (Olchowik, et. al., 2015), consistent with previous research by Faraldo-Garcia and colleagues (2012).

Faraldo-Garcia and colleagues (2012) observed that participants, ranging from 16 to 81 years old, had equilibrium and strategy differences between sexes among NeuroCom conditions and, interestingly, found a higher incidence of falls among female participants under test conditions (Wolfson, Whipple, Derby, Amerman & Nashner, 1994; Olchowik, et. al., 2015).

In contrast, another study found sex differences in fall risk under certain conditions, such as indoor versus outdoor (where men were more likely to fall outdoors), on icy surfaces, or during vigorous activity; but no differences were noted during routine walking (Duckham, Procter-Gray, Hannan, Leveille, Lipsitz & Li, 2013). Additionally, sex differences have been observed in the timed up and go (TUG) test, also sometimes referred to as the get up and go (GUG) test, such that females produced slower overall times to complete the test, suggesting a slower gait and possibly more difficulty standing from a seated position without assistance (Vereeck, Wuyts, Truijen & Van de Heyning, 2008). Previous research by Tseng and colleagues (2014) proposed body composition as a driving factor for sex differences in balance measures, such that women had a higher incidence of disability and falls due to their increased body fat and body composition pattern (Sternfeld, Ngo, Satariano & Tager, 2002; Visser, Goodpaster, Kritchevsky, Newman, Nevitt, Rubin, Simonsek & Harris, 2005). Tseng and colleagues (2014) examined older adults by comparing a composite score of physical measures, including chair stands, walking tests, and standing balance,

with total body composition (Tseng, et. al, 2014). Researchers attributed strength and more muscle mass with driving higher performance in males, while controlling for age, height, and race (Tseng, et. al, 2014). However, this study examined healthy older adults, and did not evaluate for more extensive balance measures or for common ailments in older adults including movement disorders, nor did they collect baseline measures to evaluate change or track such changes over time. While body fat mass could be an important contributing factor, more research in this still needs to be done before defining any causal relationships.



*Figure 1.* NeuroCom Balance Master Apparatus

## *1.2 Balance and Pain*

Research has also started to link balance with other prominent conditions in the older adult population, such as pain. Balance can affect the physical and psychosocial domains of pain conditions and result in avoidance behaviors, psychosocial distress, and physical deconditioning, all of which can lead to or exacerbate CLBP (Boyd & Stevens, 2009; Bevers, Watts, Kishino & Gatchel, 2016; Hulla, Gatchel & Liegey-Dougall, 2017). The perception of pain intensity, perceived physical function level, balance, and sleep-quality are all associated with pain outcomes, where more educated and/or positive patients typically result in greater ideal pain management outcomes (Lamb, et. al, 2000; Leveille, Ling & Hochberg, 2001; Leveille, Bean, Bandeen-Roche, Jones, Hochberg & Guralnik, 2002; Morgan, Parker, Alvarez-Jimenez & Jorm, 2013; Stubbs, Binnekade, Eggermont, Sepehry, Patchay & Schofield, 2014; Hulla, Moomey, Garner, Ray & Gatchel, 2016; Lee, Biggan & Ray, 2016). Although research has uncovered certain sex differences in pain and balance, the mechanisms of action driving these differences are not fully understood. Many different explanations have been proposed, such as hormonal influences, stereotypical gender roles, genetic factors, processing of pain stimuli, strength, and activity level (Wise, Price, Myers, Heft & Robinson, 2002; Chin & Rosenquist, 2008; Fillingim, King, Ribeiro-Dasilva, Rahim-Williams & Riley, 2009; Manson, 2010; Fowler, Rasinski, Geers, Helfer & France, 2011; Vieira, et. al., 2012; Bartley & Fillingim, 2013; Vincent,



Warnaby, Stagg, Moore, Kennedy & Tracey, 2013). There are genetic and hormonal differences contributing to the disproportionate rate of injury and disability. Therefore, defining the mechanisms responsible is imperative to developing the most effective preventative and treatment methods (Bartley & Fillingim, 2013).

### *1.3 Sex Differences in Pain*

Researchers have observed sex differences in pain processing, biologically and psychosocially. For example, women tend to engage in catastrophizing behaviors while also participating in social support and positive self-statements more than men do (Keogh & Eccleston, 2006; Fillingim, et. al., 2009; Racine, Tousignant-Laflamme, Kloda, Dion, Dupuis & Choiniere, 2012; Bartley & Fillingim, 2013). Catastrophizing behaviors, specifically pain catastrophizing, have been found to predict pain interference and intensity ratings in females with chronic pain (Darnall & Sazie, 2012). These findings could indicate that behavioral intervention targeting catastrophizing behaviors could be an important factor in pain management, particularly in females (Darnall & Sazie, 2012). Female patients may be more receptive to psychosocial interventions such as group therapy or positive reframing and their role long-term pain management requires further exploration. However, other research indicates that engagement in catastrophizing is not a sex difference, but rather a personality difference (Racine, et. al., 2012; Bartley & Fillingim, 2013). Additionally, previous research reports

that women experience pain more intensely, more frequently, and for longer durations than reported by men (Vieira, Santos Garcia, da Silva, Araujo, Jansen & Bertrand, 2012; Bartley & Fillingim, 2013; Bulls, Freeman, Anderson, Robbins, Ness & Goodin, 2015). Women have also reported more reluctance to seek intensive treatment, such as surgery, and report lower quality-of-life scores when suffering from severe back pain (Karlson, Datroy, Liang, Eaton & Katz, 1997; Racine, et. al., 2012; Stromqvist, Stromqvist, Jonsson & Karlsson, 2016; Triebel, Snellman, Sanden, Stromqvist & Robinson, 2017). Previous research concerning sex differences in pain perception also indicates women are disproportionately affected by certain pain conditions, such as migraines and fibromyalgia (Greenspan, et. al., 2007; Bartley & Fillingim, 2013; Bulls, et. al., 2015). The fact that women are disproportionately affected by numerous painful conditions and report more intense pain experiences yet are still more reluctant to seek proper medical intervention is concerning. Potential explanations could include financial concerns regarding skyrocketing medical costs or possibly fear of acknowledging a chronic pain condition.

Pain is prominent in older adults, and often undertreated. Roughly, 80% of adults in the United States (US) will experience a back pain episode in their lifetimes, with approximately 20% reoccurring within 6-months (Tuakli-Wosornu, et. al., 2016). Low back pain (LBP) is the most prevalent pain condition, with more occurrences than knee, neck, and migraine headache pain

(Blackwell, Lucas & Clarke, 2014; Bevers, et. al., 2016). Specifically in older adults, CLBP can lead to increased levels of depression and anxiety, as well as decreased productivity and quality-of-life (Lopez-Martinez, Esteve-Zarazaga & Ramirez-Maestre, 2008; Boyd & Stevens, 2009; Moore, et. al., 2011; Theou, et. al., 2011; Hull, Kneebone & Farquharson, 2012; Macfarlane, et. al., 2012; Regan, Kearner, Savva, Cronin & Kenny, 2013; McGuire, Nicholas, Asghari, Wood & Main, 2014; Schulz, et. al., 2015; Bevers, et. al., 2017). LBP is a leading cause of disability and an enormous economic burden, compiling billions of dollars in care costs and lost productivity (Qaseem, et. al., 2017). However, older adults can take measures to combat age-related physical declines such as sustaining an active lifestyle (Hulla, Gatchel & Liegey-Dougall, 2018). Declines in physicality are consequential with age, although research has shown a vital role of physical activity in combatting this age-related decline (Takeshima, et. al, 2013; Bevers, Brecht, Jones & Gatchel, 2018).

#### *1.4 Special Concerns for Older Adults*

It is critical that this population have access to education and resources on how to maintain healthy habits, including balance and strength exercises, pain management, and injury prevention. Patient education has improved over time although, particularly for older adults, they are often prescribed pharmacological maintenance methods rather than physical ones (McFarlane, et. al., 2012; Polatin, Bevers & Gatchel, 2017). Due to the high average of number of medications older

adults take regularly (Macfarlane, et. al., 2012; Bevers, et. al., 2017), remaining sensitive to the individuals' physical abilities, as well as the physiological changes that occur in metabolizing and synthesizing certain compounds is a critical concern when designing a management program that includes a pharmacological component (Polatin, Bevers & Gatchel, 2017). It is of the utmost importance that effective pain management interventions and other strategies for older adults are identified and implemented, not relying on pain medications or vigorous exercise.

In addition to education and access, attitude and balance are two major, and intertwined, facets to be addressed. Improved balance may stimulate attitude improvement, and possibly encourage more activity that is physical. Consequent increases in strength and stability could lower the risk of falls and subsequent injury, as well as alleviate pain or aid in pain management programs. In addition to these concerns, the economic burden (both for the individual and society) is projected to be almost \$55 billion in the US alone by 2020 (Davis, et. al., 2010; Duckham, et. al., 2013; Burns, Stevens & Lee, 2016; CDC, 2016). Furthermore, it is insufficient to assume that mobility problems can be remedied with use of walking aids or wheelchairs alone. We have relied on such mobility devices for many years, and yet older adults continue to fall frequently (Hughes, Kneebone, Jones & Brady, 2015; CDC, 2017). While these methods can surely help, particularly when recovering from surgery or an injury, we can parse out root causes for balance deficits and design treatment modalities to effectively increase

stability and, therefore, provide a better psychosocial standing and overall quality-of-life for the patient (Takeshima, et. al, 2013; Gabriel, et. al., 2017).

Considering mobility issues are a leading contributor to disability in older adults, it makes sense that balance measures should continue to be explored (Takeshima, et. al, 2013; US Department of Health and Human Services, 2014; Gabriel, Sternfeld, Colvin, Stewart, Strotmeyer, Cauley, Dugan & Karvonen-Gutierrez, 2017). Additionally, most research has been conducted in younger populations or within groups that ranged into older adulthood. It would be of benefit to evaluate for any sex differences specifically in older populations for a number of reasons. Firstly, as previously discussed, fall-risk can increase with age, and knowing that older adults continually face costly and debilitating injury resulting from falls makes balance an important priority. As some previous work has indicated, there are sex differences in the frequency and intensity of fall-injuries, yet the mechanism behind these conclusions is unclear.

As it stands, there are many questions to be answered regarding how to best treat, manage, and prevent injury and disability in older adults. As the population ages, issues that affect the older adult populations are garnering more attention. The US Census Bureau has projected the older adult population to comprise 20% of the total US population by 2020, and 24% by 2060 (Colby & Ortman, 2014; U.S. Census Bureau, Ortman, Velkoff & Hogan, 2014; Hulla, Gatchel & Liegey-Dougall, 2017). These projections highlight the need for health

research geared toward older adults, assisting with age-related concerns like balance, mobility, and overall quality of life.

## Chapter 2

### Methods

#### *Participants*

Participants were recruited from the local Arlington, Texas community via word-of-mouth, doctor recommendations, alumni, and/or informative presentations about the Center for Healthy Living and Longevity (CHLL) on the University of Texas at Arlington (UTA) campus at a variety of community locations. Each participant was required to travel to the UTA campus CHLL lab for testing at the beginning and end of each long semester. Participants were required to produce written physician approval to participate in testing and physical interventions, in addition to signing informed consent papers adhering to the Institutional Review Board (IRB)-approved protocol (see Appendix D). Upon completion of the required paperwork, participants were assigned a unique identification number (P-number) for confidentiality purposes, pursuant to IRB protocols. This study was approved by the University of Texas at Arlington (UTA) Institutional Review Board (IRB) protocol: 2016-0117.6 (see Appendix E for IRB approval letter).

#### *Materials*

##### ***2.1 NeuroCom Balance System***

The NeuroCom Balance System measured balance by producing several scores relating to strategy, equilibrium, and sensory analyses. A composite score reflecting the amount of pressure and sway displayed during a series of trials was also computed. The apparatus consists of a three-sided surround with a force plate equipped to remain stable or move depending on the trial condition. The participant was strapped into a cushioned harness secured to stable support bars for safety, ensuring they would not fall during testing. The assessment measured postural control over six conditions, with three trials per condition (called the Sensory Organization Test [SOT]) by assessing for visual, vestibular, and somatosensory input. The SOT began with a baseline measure in which participants were on a fixed force plate with a stable surround and normal vision. The second condition was the same as the first except participants were asked to close their eyes. In the third condition, the surround became mobile, while the force plate remained stable and vision was normal. The fourth condition released the force plate so it could sway according to the participants' movements with a fixed surround and normal vision. The fifth condition was the same as the fourth, but with absent vision. The last condition released the force plate with a moving surround with normal vision.

Equilibrium scores were quantifications of postural stability across the trials of each condition, producing a score for each condition and an overall average used for analysis. A higher score indicated better postural stability. The

composite score averaged the first two conditions and then added them to the remaining four conditions, and divided by the total number of trials. A higher composite score represented better overall balance. Sensory analysis was broken down to assess somatosensory input by producing a ratio of an average equilibrium score from pairs of conditions one and two. Visual scores also use this ratio for conditions one and four, and vestibular scores are the ratio of conditions one and five. Each of these sensory input ratios represented the participants' ability to use the respective system to maintain balance where a higher score indicated more input was used more effectively. Strategy preference scores examined the amount of movement in the ankles and hips used to maintain balance during trials. Higher scores represented more normalized strategies, being ankle dominant and progressing through the hips as instability increased.

## ***2.2 PROMIS 29 Assessment***

The Patient-Reported Outcomes Measurement Information System (PROMIS-29) is a digital format self-report survey constructed to measure perceived physical function, anxiety, depression, fatigue, pain interference, sleep disturbance, and ability to participate in social activities. This measure has been repeatedly validated and widely used to measure these psychosocial variables. The present study used depression scores (high scores indicate higher levels of depressive symptoms), pain interference scores (higher levels indicate more pain



interference), and perceived physical function scores (higher scores indicate better function). The PROMIS-29 assessment is located in Appendix B.

### ***2.3 Senior Fit Test***

Participants also participated in a battery of physical measures via the Senior Fit Test (SFT). The SFT measured upper and lower body strength, endurance, and flexibility by evaluating the amount of bicep curls, grip strength, chair stands, walking distance, a step test, standing from a chair to walk 8-feet (TUG), and sit and reach measures in timed trials. The present study used chair stands (higher scores indicated more chair stands completed in 30 seconds) and TUG times (where higher scores represented slower times to complete the task). Participants were free to decline any measure they were not comfortable or physically able to complete at any time. The SFT scorecard is located in Appendix C.

### ***2.4 CLBP Classification***

Participants were required to indicate their current pain status on a two-question form explaining the NIH definition of CLBP. In accordance with the NIH definition, participants must have indicated “they have had low-back pain for at least three months or more” and they “have had low back pain for at least half the days in the past six months” to be determined a CLBP patient in this study (see Appendix A). If both requirements are not met, the participant was determined to be Non-CLBP.

## Procedure

Participants provided physical approval, informed consent, and demographic information to experimenters. All participants were assigned a participant number (P-number) to de-identify data and protect patient data. They then completed the NIH CLBP inventory to assess if the participant met the requirements to be classified as a CLBP patient in this study. All participants then completed the PROMIS 29 assessment online, the SFT, and the NeuroCom balance assessment pre-test in the CHLL facility. Participants were also asked a series of demographic questions including height, weight, age, education level, about certain pre-existing medical conditions, and medications taken. Answers were recorded manually and filed by P-number.

Testing began using the online PROMIS 29 survey. To begin the physical tests, the participant was secured to the NeuroCom apparatus with a vest to prevent injury, and stood in a three-sided surround enclosure on a flat surface with a force plate. Participants completed all six conditions with three trials per condition, while NeuroCom software recorded and analyzed balance and stability. Participants then completed the SFT including: timed chair stands – where the participant was seated in a chair and, in 30-seconds, they stood up from a seated position as many times as possible; the timed get up and go (TUG) test – where participants rose from a seated position and were timed walking 8-feet and returned to the seated position; bicep curls – using a dumbbell and typically their

dominant arm, the participant curled the weight as many times as possible; a step test – where the participant marched in place and steps were counted for 2-minutes; back scratch test where participants attempted to touch their fingers behind their backs, reaching one hand downward over the shoulder and the other hand upward from the waist; a 6-minute walk wherein the number of yards traveled on a track is recorded; and a flexibility sit-and-reach test where participants tried to reach their toes from a seated position. If at any time participants felt uncomfortable they could stop or decline testing measures.

### Chapter 3

#### Results

Data used for analyses were archival data consisting of every participants' first measurements from Fall 2015 through Fall 2017 collected at the CHLL ( $N = 144$ ). There were 39 males and 104 females with 1 missing value. There were 98 Non-CLBP and 42 CLBP patients with 4 missing values. There were 29 male and 69 female Non-CLBP participants and there were 9 male and 33 female CLBP participants. Descriptive statistics for all continuous variables can be found in Table 1-1. Data were screened for missing values, normal distributions, outliers, and implausible values. Data were normal and did not require any transformations. No variables used in the analysis exceeded more than 5% of missing cases. Assumptions for statistical tests were met unless otherwise noted in their respective section. Analyses were conducted using SPSS version 25

including the PROCESS macro. Unfortunately, a reliable tracking method for medications was not in place at the time of this study and as such, this variable could not be used or controlled for.

Table 1-1

*Descriptive Statistics*

Variable	Total				Females			Males		
	N	Missing	M	SD	N	M	SD	N	M	SD
Age	143	1	73.96	7.22	104	73.17	7.07	39	76.05	7.31
TUG	141	3	7.70	2.47	103	7.49	2.42	38	8.26	2.55
Chair Stands	140	4	11.63	4.53	102	12.08	4.16	38	10.44	5.28
Depression	142	2	47.18	6.21	102	47.75	6.24	39	45.85	5.97
Pain Interference	142	2	51.96	8.33	102	51.71	8.18	39	52.51	8.86
Physical Function	142	2	46.06	6.98	102	46.70	7.19	39	44.36	6.26
Composite	144	0	73.51	8.12	104	74.10	7.97	39	72.13	8.48
Somatosensory	144	0	94.47	4.73	104	94.92	4.82	39	93.18	4.32
Visual	144	0	86.30	8.93	104	86.01	9.41	39	86.85	7.60
Vestibular	144	0	64.72	15.64	104	66.22	14.93	39	60.90	17.16
Strategy	144	0	98.36	10.30	104	98.08	11.02	39	99.74	7.25
Equilibrium	138	6	77.70	6.49	99	78.06	6.47	38	76.93	6.54

*Power Analysis*

*A priori* power analysis, using G\*Power 3.1.9.2, was conducted prior to the proposal, requiring a medium effect size of .15 with a regression coefficient of 2.03, indicated a sample size of  $N = 109$  was necessary to achieve significant results at a probability of error  $\alpha = 0.05$ . For analysis of variance (ANOVA) models, a sample size of  $N = 128$  was required for a medium effect size of .25 with an  $F$  coefficient of 3.92, at a probability of error  $\alpha = 0.05$ . Our sample

consisted of  $N = 144$ , therefore sufficient power was achieved for regression and ANOVA models.

#### *Sex differences in Balance Measures*

To examine sex differences in balance measures (strategy, equilibrium, visual input scores, somatosensory input scores, vestibular input scores, number of chair stands, and TUG times), a multiple analysis of covariance (MANCOVA) was conducted. The Box's M test was significant,  $F(28, 16207.39) = 1.82, p = .005$ , indicating heterogeneity of covariance across groups. Levene's test values were not significant for any of the variables. As such, Pillai's Trace was reported for the analysis. When controlling for age and pain interference scores, there was not a significant effect of sex on the balance measures, Pillai's Trace  $F(7, 122) = 1.79, p = .10, \eta_p^2 = .09$ . Individual relationships between sex and the predictors were also examined for any significant relationships. Chair stands were the only significant relationship,  $F(1, 128) = 3.77, p = .05, \eta_p^2 = .03$ , such that females completed more chair stands ( $M = 12.28, SD = 3.97$ ) than males ( $M = 10.57, SD = 5.39$ ). Somatosensory input,  $F(1, 128) = 3.08, p = .08, \eta_p^2 = .02$ , was approaching significance, with females having higher somatosensory scores ( $M = 94.94, SD = 4.90$ ) than males ( $M = 93.28, SD = 4.20$ ).

#### *Sex differences in Pain Measures*

To examine sex differences in pain measures (pain interference scores and perceived physical function scores), a MANCOVA was conducted. The

Box's M test was not significant,  $F(3, 94025.53) = .58, p = .63$ , indicating homogeneity of covariance across groups. Levene's test values were not significant for any of the variables indicating homogeneity of variance was met. When controlling for age and depression scores, there was not a significant effect of sex on the combined pain measures,  $\lambda F(2, 136) = 2.23, p = .11, \eta_p^2 = .03$ . However, there was a significant difference in perceived physical function between the sexes,  $F(1, 137) = 4.35, p = .04, \eta_p^2 = .03$ , such that females ( $M = 46.70, SD = 7.19$ ) reported higher perceived function than males ( $M = 44.36, SD = 6.26$ ). Pain interferences scores were not significantly different by sex,  $F(1, 137) = 1.66, p = .20, \eta_p^2 = .01$ .

#### *Sex and Balance as predictors of CLBP*

To address whether sexes were disproportionately classified as CLBP in our sample, descriptive statistics were analyzed for percentages. Our sample consisted of 39 males, 9 (23.7%) were classified as CLBP and 29 (76.3%) were Non-CLBP with one missing value. There were 104 females, 33 (32.4%) classified as CLBP and 69 (67.6%) were Non-CLBP with two missing values. A chi-square test of independence was conducted to see if the counts were significantly different from the expected values, finding no significant associations,  $\chi^2(1, N = 140) = .99, p = .32$ .

To examine if sex and balance composite scores were significant predictors of CLBP, a binary logistic regression was conducted. Continuous

variables were standardized using  $z$ -scores. A hierarchical method was used to enter variables wherein the covariates of age and depression scores were added on the first step. The second step consisted of the predictor variables, sex and balance composite scores. The third step contained the sex and balance interaction term.

The main effects model controlling for age and depression scores with sex and balance composite scores was not significant,  $\chi^2(4, N = 133) = 6.50, p = .17$  (Cox & Snell  $R^2 = .05$ , Nagelkerke  $R^2 = .07$ ). Composite scores did not significantly predict CLBP when controlling for sex, age, and depression scores,  $b = .07, SE = .20$ , wald  $\chi^2(1) = .12, p = .72$ . Additionally, when controlling for composite scores, age, and depression scores, sex did not significantly predict CLBP,  $b = -.24, SE = .46$ , wald  $\chi^2(1) = .29, p = .59$ . Odds ratios for composite scores showed that those with poor balance were 1.07 times more likely to develop CLBP than those with better balance scores (OR = 1.07, 95% CI [.73, 1.58]). Odds ratios for sex showed females were .78 times more likely to develop CLBP than were males (OR = .78, 95% CI [.32, 1.92]). The interaction term between sex and composite scores was added and the model was significant,  $\chi^2(5, N = 133) = 11.95, p = .04$  (Cox & Snell  $R^2 = .08$ , Nagelkerke  $R^2 = .12$ ). The interaction term was significant,  $b = -1.30, SE = .66$ , wald  $\chi^2(1) = 3.88, p = .05$ . Neither composite scores  $b = 2.40, SE = 1.25$ , wald  $\chi^2(1) = 3.68, p = .06$ , or sex,  $b = -.25, SE = .49$ , wald  $\chi^2(1) = .27, p = .60$ , were significant predictors of CLBP

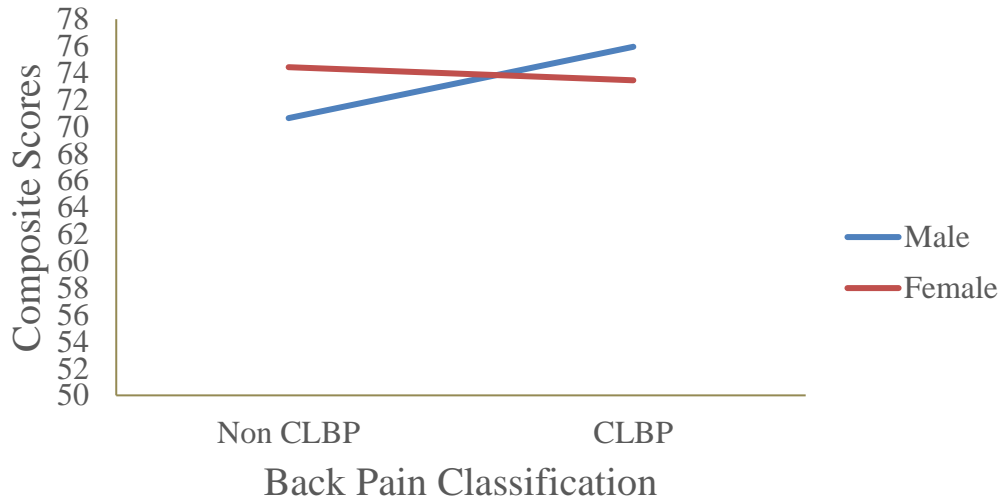
independently, though composite scores were approaching significance with inclusion of the interaction term in the model. To probe this interaction, we examined the effects of composite scores on CLBP at levels of sex (male and female) while controlling for age and depression scores. The effect of overall balance on CLBP was not significant for females,  $b = -.02$ ,  $SE = .03$ ,  $z = -.83$ ,  $p = .41$ , though this effect was approaching significance for males,  $b = .14$ ,  $SE = .08$ ,  $z = 1.80$ ,  $p = .07$ ). The effects of sex on CLBP at levels of composite scores (low -1SD, mean, high +1SD) were also examined using PROCESS. At low overall balance scores there was not an effect of sex, though it was approaching significance,  $b = 1.52$ ,  $SE = .88$ ,  $z = 1.71$ ,  $p = .09$ . At mean levels of overall balance ( $b = .25$ ,  $SE = .49$ ,  $z = .52$ ,  $p = .60$ ) and high levels of overall balance ( $b = -1.00$ ,  $SE = .71$ ,  $z = -1.41$ ,  $p = .16$ ) there were not any effects of sex. These results suggest that males with poor balance may be more likely to develop CLBP.

Next, the moderating relationship of CLBP on sex and balance composite scores was assessed, while controlling for age and pain interference scores using PROCESS. All continuous measures were mean centered for analysis. The overall model was not significant,  $F(5, 133) = 1.20$ ,  $p = .31$ ,  $r^2 = .04$ . Additionally, inclusion of the interaction term did not improve the model,  $\Delta r^2 = .03$ ,  $F(1, 133) = 3.54$ ,  $p = .06$ , and was not significant,  $b = -6.46$ ,  $SE = 3.43$ ,  $t(138) = -1.88$ ,  $p = .06$ . However, when participants were Non-CLBP, the conditional effect of sex on composite scores was significant,  $b = 3.79$ ,  $SE = 1.77$ ,  $t(139) = 2.14$ ,  $p = .03$ .



Non-CLBP males ( $M = 70.83$ ,  $SD = 9.17$ ) had lower balance composite scores than Non-CLBP females ( $M = 74.51$ ,  $SD = 7.75$ ). CLBP participants did not produce the same effect,  $b = -2.50$ ,  $SE = 2.98$ ,  $t(139) = -.84$ ,  $p = .40$ . Females with CLBP ( $M = 73.27$ ,  $SD = 7.19$ ) had lower balance composite scores than males ( $M = 76.00$ ,  $SD = 4.80$ ), though this relationship was not significant. As seen in Figure 2, females scores remain relatively stable across levels of back pain, where males overall balance composite scores increase with the presence of CLBP compared to Non-CLBP. To assess if composite scores were significantly different by sex by CLBP classification an independent  $t$ -test was conducted. Levene's test was not significant for Non-CLBP and CLBP groups. Results indicated that composite scores were significantly different between males and females that were Non-CLBP,  $t(96) = -2.03$ ,  $p = .05$ , 95% CI of the difference [-7.28, -.08],  $d = .43$ , such that Non-CLBP females had better overall balance ( $M = 74.51$ ,  $SD = 7.75$ ) than did Non-CLBP males ( $M = 70.83$ ,  $SD = 9.17$ ). There was not a significant difference between the sexes that were classified as CLBP,  $t(40) = 1.07$ ,  $p = .29$ , 95% CI of the difference [-2.43, 7.88]. Additionally, an independent  $t$ -test was conducted to examine if composite scores were significantly different by CLBP classification within each sex. Levene's tests were not significant for either sex. Results indicated there were no significant differences for CLBP and Non-CLBP males,  $t(36) = -1.61$ ,  $p = .12$ , 95% CI of the

difference [-11.67, 1.33], or CLBP and Non-CLBP females,  $t(100) = .77, p = .44$ , 95% CI of the difference [-1.95, 4.42].



*Figure 2.* Conditional Effects of Sex on Composite Scores by CLBP Classification.

#### Chapter 4

#### Discussion

The relationship of sex, balance, and pain is a complicated endeavor that must continue to be researched and addressed to develop the most effective pain prevention and treatment strategies, especially for older adults. This population faces unique concerns and high rates of pain that require customizable treatment options to suit each individuals abilities and needs while resulting in the best possible outcomes. The purpose of this study was to distinguish how these domains work with each other within older adult populations, specifically

focusing on sex differences in balance measures; sex differences in pain measures; if CLBP was a moderator of the sex and balance relationship; and to determine if sex and balance were significant predictors of CLBP likelihood.

The current study did not find an overall effect of sex on balance measures as a composite outcome that included chair stands, the TUG test times, somatosensory input scores, visual input scores, vestibular input scores, equilibrium, and strategy. Chair stands were significantly different by sex, where contrary to the hypothesis, females completed more chair stands on average than did males, supporting previous findings that chair stands are a predictor of balance and physical ability (Granacher, Gollhofer & Kriemler, 2010; Hulla, Gatchel & Liegey-Dougall, 2017). Chair stands are an activity that most people engage in throughout the day and could possibly be a beneficial exercise to practice completing properly to improve balance and function, particularly as adults age. However, the findings were in contrast to previous works that found men to display more physical ability and postural control (Von Heideken-Wagert, Gustafson & Lundin-Olsson, 2009; Tseng, et. al., 2014). The present sample consisted of adults that tend to engage in regular exercise and as such, may have influenced the results. Additionally, somatosensory input was approaching significance, with females displaying higher levels of input on average. These findings are in agreement with females displaying overall better balance scores than males in this study, though this was not a significant relationship. It may be

that the females in our sample are more aware of their bodies' movement and balance and it could be interesting to evaluate their physical activity background to look for those who were involved in activities that required stability and body awareness like dance or gymnastics. It is possible that engagement in such activities, even earlier on in life, contribute to lasting postural control and stability. Furthermore, the females that tend to participate in the physical intervention program often do so to engage in social interaction with other older adults. It is possible that the females often recruit their husbands to also attend the exercise sessions and our study to increase their social interaction or for additional support. Overall, this aim was partially supported, as we found significant differences in chair stands but did not find other sex differences in balance such as equilibrium scores or TUG times.

The second aim of the current study did not support the established relationships of sex differences in pain, as measured collectively with pain interference scores and perceived physical function scores. Perceived physical function scores were significantly different between the sexes, such that females perceived their function as better on average, contrary to what was hypothesized for this test. There were no significant sex differences in pain interference. These results are contrary to established sex differences in pain measures and may possibly be affected by our sample of older, predominantly Caucasian, educated adults in the immediate geographic area (Vieira, Santos Garcia, da Silva, Araujo,

Jansen & Bertrand, 2012; Bartley & Fillingim, 2013; Bulls, Freeman, Anderson, Robbins, Ness & Goodin, 2015). Previous research has found that women tend to engage in more positive reframing and thinking activities, particularly with social support, and it may be that our female participants are engaging in regular social support and thus, are more positive regarding their daily function (Keogh & Eccleston, 2006; Fillingim, et. al., 2009; Racine, Tousignant-Laflamme, Kloda, Dion, Dupuis & Choiniere, 2012; Bartley & Fillingim, 2013).

The third aim found sex and balance composite scores did not significantly predict CLBP likelihood individually; however, the interaction term was significant which suggests that particular levels of each factor must be present to cause an effect. This study found that more females were classified as CLBP than were males, though these counts were not significantly different from what was expected, or from each other. The final aim was not supported, finding that composite scores and sex were not significant predictors of CLBP and by comparison, females were not disproportionately affected by CLBP classification. The conditional effects of composite scores on CLBP were significant for males but not females, and the conditional effects of sex on CLBP were not significant at mean or high composite scores, though they were approaching significance at low composite scores. The significant interaction term of sex and composite scores revealed that it may be possible to predict CLBP specifically in males with poor balance, and that balance differed significantly by sex when then participants

were Non-CLBP. Furthermore, there was not an overall modifying relationship of CLBP on balance and sex, though again, there was a conditional effect of sex on balance for Non-CLBP patients, where males had significantly lower balance composite scores than females, contrary to the hypothesis. This effect was not significant in CLBP participants, and females had lower balance composite scores than males, though not significantly. This finding is particularly interesting as it shows females remain stable in their overall balance composite scores despite presence of CLBP. Females saw a slight decline, though not significant, in overall balance composite scores when classified as Non-CLBP compared to CLBP. Males fluctuated more in their overall balance composite scores, displaying better balance overall when classified as CLBP compared to Non-CLBP, though these differences were not significant either. This is in contrast to the original hypothesis that predicted CLBP to have a negative relationship with overall balance, specifically that composite scores would be lower in participants with CLBP. It is interesting that these differences in balance emerge only under these specific conditions and it would be interesting to examine how these participants scores are changing over time with and without physical intervention. It may be possible that balance training could help prevent development of CLBP, specifically in males.

It is possible that sex differences observed in balance measures are far more complicated than simple group membership like CLBP classification. These

results add to the growing evidence of sex differences in balance measures as previously reported by Vereeck and colleagues (2008), Faraldo-Garcia and colleagues (2012), and Duckham and colleagues (2013). For instance, Tseng and colleagues (2014) proposed that women had a higher incidence of falls than men did due to body composition, such that women tend to store more body fat and have a different general muscular composition than men may also indicate why we did not detect differences in females balance across CLBP classifications. With support for differences in chair stands, potential strength and balance differences may persist, where males may exceed in strength standing from a seated position, and females may display better overall balance during standing. Other proposed explanations include hormonal and genetic influences, social support and mindfulness, pain processing, activity levels, and overall strength (Wise, Price, Myers, Heft & Robinson, 2002; Chin & Rosenquist, 2008; Fillingim, King, Ribeiro-Dasilva, Rahim-Williams & Riley, 2009; Manson, 2010; Fowler, Rasinski, Geers, Helfer & France, 2011; Vieira, et. al., 2012; Bartley & Fillingim, 2013; Vincent, Warnaby, Stagg, Moore, Kennedy & Tracey, 2013).

#### Limitations and Future Directions

As with any data that utilizes self-report measures, such as the PROMIS-29 used in the present study, there is room for bias and error in reporting. The data were screened for implausible and unlikely values, to which none were identified. Additionally, we had unequal sample sizes, and could not match pair each

participant. We were also limited in our sample, such that we required older adults to be able to travel to our facility in Arlington, TX at least twice per long semester, and up to three times weekly if they chose to participate in the physical activity groups led at the CHLL. As such, our participants were predominantly Caucasian, more physically fit, UTA alumni, many with advanced degrees. Furthermore, participants were strictly volunteers and our sample was not randomized or paired.

Despite the limitations of this study, we were able to elucidate some interesting aspects of sex differences in balance and pain. It is important to take a multitude of individual factors into account when designing pain management programs that will best suit each individual's needs and provide for the best possible outcomes, to which the participants' sex is an important consideration. While age related declines may dissipate effects of previously established sex differences, such as perceived physical function, or pain interference, normal aging does not seem to be solely accountable considering the variability in physical ability and psychosocial status. However, the role of exercise has obvious benefits on strength, endurance, and overall function even accounting for differences that occur with age. The current study found sex differences in balance, in accordance with previous research that found sex differences to persist in older adult populations through tests like GUG and chair stands. It is clear there are persistent sex differences in pain, though these differences may diminish with



aging, or we may be seeing declines in reporting and those seeking treatment possibly due to financial concerns.

The relationships between balance, sex, and pain should be further explored to determine how the relationships hold over time and across samples, particularly in balance domains. To expand on the current study, it would be ideal to recruit a more diverse sample, with matched participants to compare for balance components, and more equal sample sizes between the sexes to parse out any differences. It may also be advantageous to further probe each of the balance domains and how they relate to different aspects of pain. Furthermore, comparing sex differences across multiple age groups (children, adolescents, adults, and older adults) to identify if sex differences dissipate with age could be interesting. It is important that researchers continue to uncover how balance fits into the complex relationships of pain, specifically in older adults where traditional modalities of treatment can meet complications and resistance.

### Conclusion

The relationship between biopsychosocial factors of pain, sex, and balance is incredibly complex. Considering that one in three older adults falls annually, with 20-30% resulting in serious injury or disability, it is clear that we must address concerns of overall balance and fall risk for this population (Freeman, et al., 2002; Chang, Morton, Rubenstein, Mojica, Maglione, Suttorp, Roth & Shekelle, 2004; Close, 2005; Gallagher, Rapuri & Smith, 2007; Bishop, Patterson,

Romero & Light, 2010; Duckham, et al. 2013; Donath, Van Dieen & Faude, 2016; Hulla, Gatchel & Liegey-Dougall, 2017). Additionally, pain is prevalent among older adults, and CLBP is a serious and prominent condition that can lead to (further) physical deconditioning and exacerbation of related psychosocial variables such as depression and decreased quality of life (Lopez-Martinez, Esteve-Zarazaga & Ramirez-Maestre, 2008; Boyd & Stevens, 2009; Moore, et. al., 2011; Theou, et. al., 2011; Hull, Kneebone & Farquharson, 2012; Macfarlane, et. al., 2012; Regan, Kearner, Savva, Cronin & Kenny, 2013; McGuire, Nicholas, Asghari, Wood & Main, 2014; Schulz, et. al., 2015; Bevers, et. al., 2017). It is critical that research continues to examine how we can best prevent and manage pain conditions, especially in the midst of the opioid crisis. This is particularly true for older adults with their unique concerns such as increased medication use, physical deficits and deconditioning, and comorbidities. Attending to issues of pain and balance from a biopsychosocial perspective allows for consideration of a “whole person” approach in which the psychosocial effects can be addressed in conjunction with the physical experiences.

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Appendix A  
NIH Definition of CLBP

### NIH DEFINITION OF CLBP

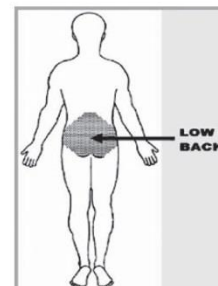
A response of greater than 3 months to Question 1

and

A response of “at least half the days in the past 6 months” to Question 2

**1. How long has low-back pain been an ongoing problem for you?**

- Less than 1 month
- 1–3 months
- 3–6 months
- 6 months–1 year
- 1–5 years
- More than 5 years



**2. How often has low-back pain been an ongoing problem for you over the past 6 months?**

- Every day or nearly every day in the past 6 months
- At least half the days in the past 6 months
- Less than half the days in the past 6 months

Appendix B  
PROMIS-29 Assessment

PROMIS–29 Profile v2.0

Please respond to each question or statement by marking one box per row.

<b>Physical Function</b>		<b>Without any difficulty</b>	<b>With a little difficulty</b>	<b>With some difficulty</b>	<b>With much difficulty</b>	<b>Unable to do</b>
1	Are you able to do chores such as vacuuming or yard work? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Are you able to go up and down stairs at a normal pace? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Are you able to go for a walk of at least 15 minutes? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Are you able to run errands and shop? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Anxiety</b>						
<b>In the past 7 days...</b>		<b>Never</b>	<b>Rarely</b>	<b>Sometimes</b>	<b>Often</b>	<b>Always</b>
5	I felt fearful .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	I found it hard to focus on anything other than my anxiety .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	My worries overwhelmed me .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	I felt uneasy .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Depression</b>						
<b>In the past 7 days...</b>		<b>Never</b>	<b>Rarely</b>	<b>Sometimes</b>	<b>Often</b>	<b>Always</b>
9	I felt worthless .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	I felt helpless .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	I felt depressed .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	I felt hopeless .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Fatigue</b>						
<b>During the past 7 days...</b>		<b>Not at all</b>	<b>A little bit</b>	<b>Somewhat</b>	<b>Quite a bit</b>	<b>Very much</b>
13	I feel fatigued .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14	I have trouble starting things because I am tired .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

PROMIS-29 Profile v2.0

<b>Fatigue</b>						
<b>In the past 7 days...</b>		<b>Not at all</b>	<b>A little bit</b>	<b>Somewhat</b>	<b>Quite a bit</b>	<b>Very much</b>
15	How run-down did you feel on average? ...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16	How fatigued were you on average? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Sleep Disturbance</b>						
<b>In the past 7 days...</b>		<b>Very poor</b>	<b>Poor</b>	<b>Fair</b>	<b>Good</b>	<b>Very good</b>
17	My sleep quality was .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>In the past 7 days...</b>		<b>Not at all</b>	<b>A little bit</b>	<b>Somewhat</b>	<b>Quite a bit</b>	<b>Very much</b>
18	My sleep was refreshing .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19	I had a problem with my sleep .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20	I had difficulty falling asleep .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Ability to Participate in Social Roles and Activities</b>						
		<b>Never</b>	<b>Rarely</b>	<b>Sometimes</b>	<b>Usually</b>	<b>Always</b>
21	I have trouble doing all of my regular leisure activities with others .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22	I have trouble doing all of the family activities that I want to do .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23	I have trouble doing all of my usual work (include work at home) .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24	I have trouble doing all of the activities with friends that I want to do .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Pain Interference</b>						
<b>In the past 7 days...</b>		<b>Not at all</b>	<b>A little bit</b>	<b>Somewhat</b>	<b>Quite a bit</b>	<b>Very much</b>
25	How much did pain interfere with your day to day activities? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26	How much did pain interfere with work around the home? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27	How much did pain interfere with your ability to participate in social activities? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28	How much did pain interfere with your household chores? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**PROMIS-29 Profile v2.0**

**Pain Intensity**

**In the past 7 days...**

29	How would you rate your pain on average?.....	<input type="checkbox"/> 0 No pain	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10 Worst imaginable pain
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Appendix C  
Senior Fit Test Scorecard

Date: \_\_\_\_\_

Participant #: \_\_\_\_\_

M / F

DOB: \_\_\_\_\_

Age: \_\_\_\_\_

Height: \_\_\_\_\_ Weight: \_\_\_\_\_

Bicep Curl(#in 30 s)				R/L
Chair Stands (# in 30 sec)				
8 ft up and go (sec)				
2 min step test				
Sit-&-Reach (inches)	+/-		+/-	R/L
Back Scratch (inches)				R/L
Grip Strength (Kg)				R/L
6 Min Walk (yards)				C



Appendix D  
Informed Consent Document

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**PRINCIPAL INVESTIGATOR**

Dr. Robert J. Gatchel, Department of Psychology, College of Science, 817-272-2541,  
Gatchel@uta.edu

**TITLE OF PROJECT**

Effects of a seated exercise intervention simulating activities of daily living on factors associated with fall risk.

**INTRODUCTION**

Before you say that you will be in this research study, you need to read this Form. It is important for you to understand all the information in this Form. This Form will tell you what the study is about and how it will be done. It will tell you about some problems that might happen for you during the study. When you read a paper like this to learn about a research study, it is called "Informed Consent". The people who are doing this research study are giving you very important information about the study. When you give your consent for something, it is the same as giving your permission. This Consent Form may contain words that you do not understand. Please talk to someone from the research staff if you have questions. Do not sign this Consent Form unless all your questions have been answered and you feel comfortable with the information you have read. You will be given a copy of the Form to keep.

**PURPOSE**

The specific purposes of this research study are as follows:

We want to learn about the role of exercise in preventing falls in healthy older adults.

We want to observe if fall-risk and pain are related.

We want to observe if exercise is an effective way to manage pain.

**DURATION**

You will be in the study for approximately 16 weeks, with those in the Exercise Group receiving 13-weeks of intervention. However, due to Holiday/University breaks, there may be fewer interventions sessions (however, that will not affect your continued participation in the study).

**NUMBER OF PARTICIPANTS**

1

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The number of anticipated participants in this research study is 500.

### **PROCEDURES**

All of the procedures that are being done in this study are approved for healthy older adults: nothing is considered experimental. Before you can participate in the study, you must get your medical doctor's written permission for you to participate.

If you qualify to be in the study and consent to take part in it, you will be given an appointment to return. On that day, you will be asked to complete questionnaires, which will ask you questions about your health and about how and when you interact with others. On the same day, you will be asked to complete initial baseline testing of your strength, weight, balance, walking speed, cognitive ability, environment that you live in, sociability, social support, and demographics. We are also interested in individual differences that are related to the way you move.

#### Comprehensive Fall Risk Screening Instrument (CFRSI)

The CFRSI includes five falls- risk subscales. The History Risk sub-scale includes identified falls- risk factors of history of falls, assistive device usage (such as a cane or walker), diagnosis of arthritis, and self-reported age. The Physical Risk subscale includes measures of balance and mobility, and the Medication Risk subscale includes information regarding high-risk medication use, use of multiple pharmacists, and medication side effects. The Vision Risk subscale encompasses visual acuity, optometry visits, and use/compliance of prescription lens, and the Environment Risk subscale is calculated, using information regarding hazards in the home.

#### PROMIS-29

Psychosocial outcomes are measured using the PROMIS-29, a 29-item questionnaire with 8 components, including physical function, anxiety, depression, fatigue, and sleep disturbance, satisfaction with social role, pain interference, and pain intensity. The questions on the PROMIS 29 focus on the previous 7-days. This tool is scored on a 5-point Likert scale, similar to a perceived pain scale ("on a scale of 1-5, what is your pain level?") Two of the components of the PROMIS-29 evaluate your pain (pain interference and pain intensity).

#### Sensory Organization Test (SOT) on the Neurocom Balance Master

2

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The SOT consists of six conditions (each of which is designed to test balance by challenging one of the three sensory systems used to maintain balance): eyes opened on a firm surface; eyes closed on a firm surface; eyes opened with the wall moving, based on individual sway; eyes opened on a sway- referenced support surface; eyes closed on a sway- referenced support surface; and eyes opened on a sway- referenced support surface and surround. "Sway-referenced" refers to the Neurocom's function that responds to your body's natural forward/backward sway to maintain balance.

### Gait Analysis

Researchers will also be doing a gait analysis using the Protokinetics Zeno Walkway. A gait analysis provides information on the way you walk, and may help to identify inefficiencies and weaknesses in the way you walk. You will be asked to walk normally on a pressure-sensitive walkway, where data will be collected regarding specific details of your gait. Information gained during this procedure could provide insight on the role of gait dynamics on postural control.

### Lower Extremity Dexterity (LED)

You will also be asked to control a platform attached to a spring placed on a force plate, and then compress the spring as much as possible while retaining control. This will give us information on how your feet and legs interact with, and respond to, the ground.

### Senior Fitness Test (SFT)

The Senior Fitness Test (SFT) consists of chair stands, arm curls, a timed 6-minute walk, a 2-minute step test, a seated sit-and-reach test, a "back scratch" range-of-motion test, and the 8-feet up-and-go test. Participants in the exercise intervention will experience mild physical stress as they participate in exercise. Participants in the No-SFT comparison group will not be under any added stress.

You will be randomly assigned to one of two groups:

Group 1: No-Exercise Comparison Group	Group 2: Group Exercise
---------------------------------------	-------------------------

3

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No changes to daily activity. You will take part in the initial and final study visits (questionnaires and pre-screening physical exams), but will not take part in the exercise programs which are part of this study.	Exercise (seated and standing activities) for 45-minutes, 3-times per week, for approximately 16 weeks by an instructor in the Department of Kinesiology Biomechanics and Movement Studies Lab and the adjoining gym. You will be physically monitored by a member of the research team while doing this exercise. You will also take part in the initial and final study visits (questionnaires and physical exams).
---	---

**BENEFITS**

Participating in this study will give participants in the exercise group the opportunity to participate in regular physical activity, which has been shown to have significant health benefits (including potential weight loss, and muscle strengthening) and improved quality-of-life. Participants in the comparison group, through pre- and post- data collection, will be given valuable information about their postural control, muscular strength, and cardiovascular endurance.

**RISKS**

You might experience standard muscle soreness associated with regular physical activity during this research study. To mitigate this, all exercise sessions will include an appropriate warm-up and cool-down period, which has been shown to help alleviate muscle soreness. Another risk in participating is the risk of falling during exercise. Safeguards to prevent this include having a chair available for you to rest, should you become fatigued during exercise. Trained volunteers will also be present to assist should you lose your balance.

You have the right to quit any study procedures at any time at no consequence, and may do so by informing the researcher.

**QUESTIONS**

Dr. Robert Gatchel (817-272-2541), or Tyler Garner, Research Assistant (817-272-3288)

**VOLUNTARY PARTICIPATION**

Your participation in this study is voluntary. You can decide, at any time, not to perform the exam, but still participate in the study.

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**ACKNOWLEDGMENT OF RISK**

By signing this acknowledgement of risk form, I acknowledge that I have been cleared by my physician to engage in physical activity. I also acknowledge that I have been made aware of any risks involved in participating in this study.

\_\_\_ I certify that I am aware of the risks involved in participating in this study

\_\_\_\_\_  
Subject's Name (print), Signature, Date      Operator's Name, Signature, Date

**COMPENSATION**

No compensation is available for this project.

**FINANCIAL COSTS**

There are no costs to you for being in the study.

**ALTERNATIVE PROCEDURES**

Another option is taking part in a rehabilitation or exercise program on your own without being in the study. Your other option is to not be in the study.

**CONFIDENTIALITY**

Every attempt will be made to see that your study results are kept confidential. A copy of the records from this study will be stored in a locked office or another locked area in the Department of Kinesiology for at least three (3) years after the end of this research. The results of this study may be published and/or presented at meetings without naming you as a subject. Although your rights and privacy will be maintained, the Secretary of the Department of Health and Human Services, the University of Texas at Arlington Institutional Review Board, and personnel particular to this research have access to the study records. Your medical records will be kept completely confidential according to current legal requirements. They will not be revealed unless required by law, or as stated above.

**CONTACT FOR QUESTIONS**

If you have any questions, problems, or research-related medical problems at any time, you may call the Principal Investigator, Dr. Robert Gatchel, at 817-272-2541.. Any questions you may have about your rights as a research subject or a research-related injury may be directed to the Office of Research Administration; Regulatory Services at 817-272-2105 or [regulatoryservices@uta.edu](mailto:regulatoryservices@uta.edu).

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Informed Consent Document**

**As a representative of this study, I have explained the purpose, the procedures, the benefits, and the risks that are involved in this research study:**

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**Signature and printed name of principal investigator or person obtaining consent** **Date**

**CONSENT**

By signing below, you confirm that you are 18 years of age or older and have read or had this document read to you. You have been informed about this study's purpose, procedures, possible benefits and risks, and you have received a copy of this Form. You have been given the opportunity to ask questions before you signed, and you have been told that you can ask other questions at any time.

You voluntarily agree to participate in this study. By signing this Form, you are not waiving any of your legal rights. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits, to which you are otherwise entitled.

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**SIGNATURE OF VOLUNTEER**

**DATE**

Appendix E

Institutional Review Board (IRB) Approval Letter





January 20, 2017

Dr. Robert J. Gatchel  
Psychology  
The University of Texas at Arlington  
Box 19498

**IRB No.:** 2016-0108  
**Title:** *The Effectiveness of Objective Monitoring and Exercise Intervention for Chronic Low-Back Pain Management*

**Original Approval Date:** January 20, 2016  
**Continuing Review with Modification Approval Date:** January 20, 2017  
**Expiration Date:** **January 20, 2018**

#### EXPEDITED CONTINUING REVIEW WITH MODIFICATION APPROVAL

The Chair (or designee) of the University of Texas at Arlington Institutional Review Board (IRB) reviewed and approved the status of *continuing/revise*d for the above study for a period not to exceed one year, expiring on **January 20, 2018** [45 CFR 46.109(e)]. In order for the research to continue, Continuing (annual) Review must be completed within the month preceding the expiration date indicated above. Although a reminder notice will be forwarded to the attention of the Principal Investigator (PI) at a time sufficient enough to allow for the continuation review to occur, it is the PI's responsibility to submit a Continuing Review for approval in the Profiles system prior to the expiration date.

The approved protocol modifications are as follows:

- Remove Dr. Gian-Luca Mariottini from protocol personnel

**The approved number of participants for this study is 50 (Do not exceed without prior IRB approval).**

#### INFORMED CONSENT DOCUMENT:

The IRB approved version of the informed consent document (ICD) must be used when prospectively enrolling volunteer participants into the study. All signed consent forms must be securely maintained on the UT Arlington campus for the duration of the study plus a minimum of three years after the completion of all study procedures (including data analysis). The complete study record is subject to inspection and/or audit during this time period by entities including but not limited to the UT Arlington IRB, Regulatory Services staff, OHRP, FDA, and by study sponsors (if the study is funded).

#### MODIFICATION TO AN APPROVED PROTOCOL:

Pursuant to Title 45 CFR 46.103(b)(4)(iii), investigators are required to, "promptly report to the IRB any proposed changes in the research activity, and to ensure that such changes in approved

REGULATORY SERVICES  
SERVICES

The University of Texas at Arlington, Center for Innovation  
202 E. Border Street, Ste. 201, Arlington, Texas 76010, Box#19188  
(T) 817-272-3723 (F) 817-272-5808 (E) [regulatoryservices@uta.edu](mailto:regulatoryservices@uta.edu) (W) [www.uta.edu/rs](http://www.uta.edu/rs)



research, during the period for which IRB approval has already been given, are **not initiated without prior IRB review and approval** except when necessary to eliminate apparent immediate hazards to the subject.” Modifications include but are not limited to: Changes in protocol personnel, number of approved participants, and/or updates to the protocol procedures or instruments. All proposed changes must be submitted via the electronic submission system prior to implementation. Failure to obtain prior approval for modifications is considered an issue of non-compliance and will be subject to review and deliberation by the IRB which could result in the suspension/termination of the protocol.

**ANNUAL CONTINUING REVIEW:**

Continuing review of the protocol serves as a progress report and provides the researcher with an opportunity to make updates to the originally approved protocol. Failure to obtain approval for a continuing review will result in automatic *expiration of the protocol* all activities involving human subjects must cease immediately. The research will not be allowed to commence by any protocol personnel until a new protocol has been submitted, reviewed, and approved by the IRB. Per federal regulations and UTA’s Federalwide Assurance (FWA), there are no exceptions and no extensions of approval granted by the IRB. The continuation of study procedures after the expiration of a protocol is considered to be an issue of non-compliance and a violation of federal regulations. Such violations could result in termination of external and University funding and/or disciplinary action.

**ADVERSE EVENTS:**

Please be advised that as the principal investigator, you are required to report local adverse (unanticipated) events to The UT Arlington Office of Research Administration; Regulatory Services within 24 hours of the occurrence or upon acknowledgement of the occurrence.

**TRAINING AND CONFLICT OF INTEREST DISCLOSURES:**

All investigators and key personnel identified in the protocol must have documented Human Subjects Protection (HSP) training on file AND must have filed a current Conflict of Interest Disclosure (COI) with The UT Arlington Office of Research Administration; Regulatory Services. HSP completion certificates are valid for 2 years from the completion date.

**COLLABORATION:**

If applicable, approval by the appropriate authority at a collaborating facility is required prior to subject enrollment. If the collaborating facility is *engaged in the research*, an OHRP approved Federalwide Assurance (FWA) may be required for the facility (prior to their participation in research-related activities). To determine whether the collaborating facility is engaged in research, go to: <http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>

**CONTACT FOR QUESTIONS:**

The UT Arlington Office of Research Administration; Regulatory Services appreciates your continuing commitment to the protection of human research subjects. Should you have questions or require further assistance, please contact Regulatory Services at [regulatoryservices@uta.edu](mailto:regulatoryservices@uta.edu) or 817-272-2105.



UNIVERSITY OF  
**TEXAS**  
ARLINGTON

OFFICE OF RESEARCH ADMINISTRATION  
REGULATORY SERVICES

Sincerely,

**Deborah Behan**  
**PhD, RN-BC**

Digitally signed by Deborah Behan  
PhD, RN-BC  
DN: cn=Deborah Behan PhD, RN-  
BC, o=UTA, ou=IRB Chair,  
email=dbehan@uta.edu, c=US  
Date: 2017.01.22 16:46:39 -06'00'

Deborah Behan, PhD  
Associate Clinical Professor, Nursing  
UT Arlington IRB Chair

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## Biographical Information

Kelley Bevers received her Bachelor of Arts degree in Psychology from the University of Texas at Austin in December 2012. She began her graduate career at the University of Texas at Arlington in August 2014 in the Experimental Psychology degree program with a Neuroscience & Health Psychology focus, earning her Masters of Science and is a current Doctoral candidate. Currently, Kelley studies biopsychosocial aspects of chronic low back pain in older adults in Dr. Robert Gatchel's laboratory. She is interested in animal behavior and genetics; neurodegenerative diseases such as Parkinson's and dementia; and the neurobiological and psychosocial aspects of pain and aging. She has contributed to work on genetic, environmental, and social factors for success in working dogs; neuropsychological testing in clinical environments; behavioral testing and mechanisms of addiction in pre-clinical models; and biopsychosocial aspects of pain, balance, and aging.